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09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,242	Applicant(s) HASELBECK ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

El ction/Restricti ns

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 14, 23, and 33, drawn to a purified or isolated nucleic acid, and a vector and compositions comprising the nucleic acid, classified in class 536, subclass 23.7.

II. Claims 6-7, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claim 8, drawn to a method to produce a polypeptide, classified in class 435, subclass 69.1.

IV. Claims 9 and 28, drawn to methods of inhibiting cell proliferation in an individual, classified in class 514, subclass 44.

V. Claims 10 and 29, drawn to methods to identify a compound which influences the activity of a gene product, classified in class 435, subclass 7.8.

VI. Claims 11 and 30, drawn to methods to identify a compound or nucleic acid which reduces the level or activity of a gene product, classified in class 435, subclass 6.

VII. Claims 12 and 31, drawn to methods to identify a compound which reduces the level or activity of a gene product required for cellular proliferation, classified in class 435, subclass 7.2.

VIII. Claims 13 and 32, drawn to methods to inhibit cellular proliferation, classified in class 435, subclass 29.

IX. Claims 15 and 34, drawn to methods for inhibiting the activity or expression of a gene in an operon, classified in class 435, subclass 6.

X. Claims 16 and 35, drawn to methods to identify a gene required for cell proliferation, classified in class 435, subclass 7.2.

XI. Claims 17-18 and 36-37, drawn to methods to identify a compound which inhibits cell proliferation, classified in class 435, subclass 7.2.

XII. Claims 19 and 38, drawn to methods to identify a compound with activity against a biological pathway, classified in class 435, subclass 7.1.

XIII. Claims 20 and 39, drawn to methods to identify a compound which inhibits cellular proliferation, classified in class 435, subclass 6.

XIV. Claims 21 and 40, drawn to methods for identifying the biological pathway in which a proliferation-associated gene lies, classified in class 435, subclass 7.2.

XV. Claim 22, drawn to a method for determining the biological pathway on which a compound acts, classified in class 435, subclass 7.1.

XVI. Claims 24-25, drawn to compounds which interact with a gene product, classified in class 530, subclass 350.

XVII. Claims 26 and 43, drawn to methods of manufacturing an antibiotic, classified in class 435, subclass 6.

XVIII. Claim 27, drawn to an isolated or purified nucleic acid different from that of Group I, classified in class 536, subclass 23.7.

XIX. Claim 41, drawn to a method for determining the biological pathway on which a compound acts comprising method steps different from those of Group XV, classified in class 435, subclass 7.1.

XX. Claim 42, drawn to a compound which inhibits proliferation by interacting with a gene, classified in class 536, subclass 22.1.

XXI. Claim 44, drawn to a method of administering a compound which reduces the activity or level of a gene product required for cellular proliferation, classified in class 514, subclass 42.

The inventions are distinct, each from the other because of the following reasons:

Groups I, IV, VI, VII, IX-XII, XIV-XV, and XVIII-XIX are separate and distinct from Groups II-III and V because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups II-III and V, the critical feature is a polypeptide whereas for Groups I, IV, VI, VII, IX-XII, XIV-XV the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Group I, for example, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX are separate and distinct from each of Groups VIII and XIII. Groups I, IV, VI, VII, IX-XII, XIV-XV are directed to polynucleotides whereas Groups VIII and XIII are directed to methods of using cells. The methods of Groups VIII and XIII do not recite use of the polynucleotides of Groups I or XVIII and the polynucleotides recited in Groups I and XVIII are not limited to be those for use in the methods of Group VIII or XIII. In addition, the methods of Groups IV, VI-VII, IX-XII. XIV-XV and XIX are directed to different results and recite different method steps and use of different products than the method of Groups VIII and XIII. For these reasons, each of Groups VIII and XIII is separate and distinct from each of Groups I, IV, VI, VII, IX-XII, XIV-XV, and XVIII-XIX.

Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX are separate and distinct from each of Groups XVI and XX. Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX are directed to polynucleotides whereas Groups XVI and XX are directed to compounds which interact with a gene or gene product. The compounds of Groups XVI and XX are not limited to be polynucleotides, and are therefore directed to different products than the polynucleotides of Groups I and XVIII. None of the methods of use of Groups IV, VI, VII, IX-XII, XIV-XV or XIX recites use of the compounds of Group XVI or XX, and the compounds of Groups XVI and XX are not limited to be those for use in the methods. For these reasons, each of Groups XVI and XX is separate and distinct from each of Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX.

Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX are separate and distinct from each of Groups XVII and XXI. Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX are directed to polynucleotides whereas Group XVII recites a method of making an antibiotic, wherein said antibiotic is not limited to be a polynucleotide, nor does the method recite use of a polynucleotide. Group XXI is directed to a method of administering a compound, wherein said compound is not limited to be a polynucleotide. Both the methods of Groups XVII and XXI recite different method steps, use of different products, and are directed to different results than any of the methods of Groups IV, VI, VII, IX-XII, XIV-XV and XIX , and maybe practiced without knowledge of or reference to the results of any other method. For these reasons, each of Groups XVII and XXI is separate and distinct from each of Groups I, IV, VI, VII, IX-XII, XIV-XV and XVIII-XIX.

Groups II, III, and V are separate and distinct from each of Groups VIII and XIII. Groups II, III, and V are directed to polypeptides whereas Groups VIII and XIII are directed to methods of using cells. The methods of Groups VIII and XIII do not recite use of the polypeptide of Group II and the polypeptide recited in Group II is not limited to be one for use in the method of

Group VIII or XIII. In addition, the methods of Groups III and V are directed to different results and recite different method steps and use of different products than the methods of Groups VIII and XIII. For these reasons, each of Groups VIII and XIII is separate and distinct from each of Groups II, III, and V.

Groups II, III, and V are separate and distinct from each of Groups XVI and XX. Groups II, III, and V are directed to polypeptides whereas Groups XVI and XX are directed to compounds which interact with a gene or gene product. The compounds of Groups XVI and XX are not limited to be polynucleotides, and are therefore directed to different products than the polypeptide of Group II. The methods of Groups II and V do not recite manufacture or use of the products of Groups XVI or XX, and the compounds of Groups XVI and XX are not limited to be those made by or for use in the methods of Groups II and V. For these reasons, each of Groups II, III and V is separate and distinct from each of Groups XVI and XX.

Groups II, III, and V are separate and distinct from each of Groups XVII and XXI. Groups II, III, and V are directed to polypeptides whereas Group XVII recites a method of making an antibiotic and Group XXI is directed to a method of administering a compound. Neither the antibiotic made nor the compound administered is limited to be the polypeptide of Group II. Both the methods of Groups XVII and XXI recite different method steps, use of different products, and are directed to different results than any of the methods of Groups III and V, and maybe practiced without knowledge of or reference to the results of any other method. For these reasons, each of Groups XVII and XXI is separate and distinct from each of Groups II, III, and V.

Groups I and XVIII are not related. Both Groups recite polynucleotides; however, the polynucleotides are limited to be different in each Group. As each sequence represents a different structure/product, and the Groups recite different products, they are not related.

Invention I is related to Inventions IV, VI, VII, IX-XII, XIV-XV, and XIX as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (polynucleotide) of Group I can be used in any of the methods of use of Groups IV, VI, VII, IX-XII, XIV-XV, and XIX.

Invention XVIII is not related to any of Inventions IV, VI, VII, IX-XII, XIV-XV, and XIX. The polynucleotide of Group XVIII is not limited to be one for use on any of the methods of Groups IV, VI, VII, IX-XII, XIV-XV, and XIX, and none of the methods of Groups IV, VI, VII, IX-XII, XIV-XV, and XIX recite use of the polynucleotide of Group XVIII.

Groups IV, VI, VII, IX-XII, XIV-XV, and XIX are separate and distinct. The Groups are related in that each recites use of the same polynucleotides; however, each Groups is directed to a different results and recites different method steps. In addition, the method of any Group may be performed without knowledge of or reference to the steps or results of any other Group. For these reasons, each of Groups IV, VI, VII, IX-XII, XIV-XV, and XIX is separate and distinct.

Groups II, III, and V are unrelated. The polypeptide of Group II is not limited to be one made by the method of Group III nor to be one for use in the method of Group V. The polypeptide made by the method of Group III is not limited to be the same as the polypeptide of Group II, nor is it limited to be one for use in the method of Group V. The method of Group V does not recite use of the polypeptide of Group II or the polypeptide made in the method of Group III. For these reasons, Groups II, III, and V are not related.

Groups VIII and XIII are not related. Both Groups recite methods of use of cells; however, each Group is directed to a different result and recites different method steps. In

addition, the cells use din each method are not limited to be the same cells and the methods of each Group may be performed without knowledge of or reference to the steps or results of any other method.

Groups VIII and XIII are not related to either of Groups XVII or XXI. Groups VIII and XIII are directed to methods of using cells whereas neither of the methods of Groups XVII or XXI recite use of cells. All of the Groups recite different method steps and are directed to different results.

Groups XVII and XXI are not related. The antibiotic made by the method of Group XVII is not limited to be one for administration in the method of Group XXI, and the method of Group XXI does not recite administration of the antibiotic made in the method of Group XVII. Each Group recites different method steps and sue of different products and may be practiced without reference to the steps or results of any other method.

Groups XVI and XX are not related. The compounds of each Group are limited to comprise different properties and therefore would be expected to behave differently in methods of use. For these reasons, the compounds would be expected to be different products, and are not related.

Neither of Groups XVI and XX is related to any of Groups VIII, XIII, XVII and XXI. None of the methods of Groups VIII, XIII, XVII or XXI recite use or manufacture of either of the compound of Groups XVI or XX, and neither of the compounds of Groups XVI or XX is limited to be one made by or for use in the method of any of Groups VIII, XIII, XVII or XXI. For these reasons, the Groups are not related.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, therefore restriction for examination purposes as indicated is proper. Further, because

these inventions are distinct for the reasons given above and the search required for Groups II-XXI is not required for Group I; the search for Groups III-XXI is not required for Group II, the search for Groups II-III and V-XXI is not required for Group IV, etc., restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Conclusion

Claims 1-44 are restricted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

August 15, 2002